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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,137	07/25/2000	Pramod K. Srivastava	8449-123-999	8478
20583	7590	05/18/2005	EXAMINER	
JONES DAY			YAEN, CHRISTOPHER H	
222 EAST 41ST ST			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	

1642

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/625,137

Applicant(s)

SRIVASTAVA, PRAMOD K.

Examiner

Christopher H. Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 80,81,83-92,94-96 and 104-112 is/are pending in the application.
- 4a) Of the above claim(s) 85-87 and 89-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-81,83-84,88,94-96, and 104-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

B

DETAILED ACTION

Re: Srivastava *et al*

1. The amendment filed 1/5/2005 is acknowledged and entered into the record. Accordingly, claims 1-79, 82,93,97-103, and 107 are canceled without prejudice or disclaimer.
2. Claims 80-81,83-92,94-96, and 104-112 are pending, claims 85-87, and 89-92 are withdrawn as being drawn to a non-elected invention.
3. Claims 80-81,83-84,88,94-96, and 104-112 are examined on the merits.
4. Claim 80 is examined to the extent that the term "test compound" is read as a small molecule only, and claim 112 is read to the extent that the ligand-binding fragment of $\alpha 2M$ receptor is SEQ ID No: 21 only. Applicant is required to amend claim to reflect elect subject matter.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections Maintained

6. The objection of claim 112 for the recitation of non-elected subject matter is maintained for the reasons of record. Applicant argues that the claim recites species within a genus recited in claim 80. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.
7. In response to the restriction requirement mailed 3/19/2004, applicant was required to elect a single sequence recited in claim 112 (see page 9 of action mailed

3/19/2004) as part of the claimed invention. Applicant was also informed that the election of a single sequence was not to be construed as an election of species but rather as an elected invention because each of the sequences represented different and distinct searches. In response to the restriction requirement of 3/19/2004, applicant elected SEQ ID No: 21 as part of the claimed invention and failed to raise any issue with regard to the election of a single sequence (see paper filed 6/17/2004). As such, the restriction was subsequently made final and claims 80 and 112 were examined on to the extent that the claims read on "small molecules" and "SEQ ID No: 21" as elected.

8. Therefore, because the restriction requirement has been made final, claim 112 as currently presented reads on non-elected subject matter. Appropriate correction is required.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

9. The rejection of claims 80-81,83-84,88,94-96,104-112 as lacking adequate written description with respect to small molecules under 35 USC § 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the term small molecule is conventional in the art and that one of skill in the art would readily understand that the term refers to chemical compounds that have a molecular weight of less than about 2500 amu. Applicant additionally contends that the specification provides various libraries of small molecule that are commercially available. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The specification of the instant application indicates that small molecules encompass a broad range of molecules (such as organic and inorganic molecules) and as indicated in the response filed 1/05/2005 included libraries of small molecules. However, what the instant application failed to accomplish is in fact actually identifying a small molecule by performing the claimed method. Absent such a disclosure of a small molecule, the invention is incomplete because it only provides a starting point for further discovery or research plan (see *University of Rochester v. G.D. Searle & Co.*). Without possession, or at least knowledge, of such a compound, or of a method certain to yield such a compound, the inventors could not have possessed the claimed invention (see *Vas-Cath*, 935 F3d. 1563-64).

Moreover, the term "small molecule" encompasses a genus of molecules, the specification has not provided any structural indication of the molecule or any correlation between structure and function, nor a representative number of species to fulfill the requirement under written description.

New Arguments

Claim Objections

10. Claims 80 and dependent claims thereof are objected to because of the following informalities:

- a. Claim 80 recites the term "test compound". The claim reads generically on compounds that are non-elected inventions. Applicant is required to amend the claims to recite the elected invention only.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

11. Claims 80-81,83-84,88,94-96, and 104-112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims of the instant invention are drawn to a method of identifying a compound that modulates an HSP- α 2M receptor mediated process, comprising the steps of (1) contacting a small molecule with a ligand binding fragment of α 2M receptor and a purified HSP or binding fragment thereof, and (2) measuring the level of HSP binding, uptake or antigen representation activity and comparing those levels in the absence of the small molecule.

The specification prophetically teaches a method of screening or identifying compounds, including small molecules using the claimed method but fails to specifically provide any working examples of the claimed method.

To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The method objective of claimed invention is the identification of a potential small molecule that modulate the interaction of α 2M receptor with HSP. Thus, it would be expected that one of skill in the art would be able to identify an small molecule

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without undue experimentation by using the claimed method. The instant method specifies the contacting of a small molecule with an α 2M receptor fragment and a HSP or binding fragment thereof. The specification does not teach a particular small molecule which would modulate (i.e. inhibit or enhance) the interaction between the α 2M receptor binding fragment and HSP or binding fragment thereof. The specification does not teach any structural or biochemical requirements which should be present in the genus of small molecules which would allow one of skill in the art to select a set of small molecule test compounds and subject them to the instant method with a reasonable expectation of success of identifying an agent which would modulate the interaction between the ligand binding fragment of α 2M receptor and HSP or binding fragment thereof. Further, the specification does not teach a partial structure coupled with a biochemical characteristic which would provide a reasonable expectation of success to one of skill in the art for the selection of a small molecule test agents which would modulate the interaction as claimed. Given the lack of guidance in the specification for how to find a small molecule test agent which would function as claimed, one of skill in the art would be subject to undue experimentation in order to carry out the claimed methods.

The findings in *University of Rochester v G.D. Searle & Co*, 249 F. Supp. 2d 216 (W.D.N.Y. 2002), and 358 F.3d 916, 69 USPQ.2d 1886 (BNA) (Fed Cir Feb 13, 2004) are relevant to the instant claims. The Federal Circuit upheld the decision rendered from United States District Court regarding the invalidity of U.S. 6,048,850. The claims in the '850 patent were drawn to methods for selectively inhibiting PGHS-2 activity in a human

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host, comprising administering a non-steroidal compound that selectively inhibits activity of PGHS-2. The District Court determined that the '850 patent was invalid because it did not provide an enabling disclosure of how the invention was to proceed. The court concluded that although the patent provided as assay for identifying selective PGHS-2 inhibitors, and teachings for how to use such compounds once identified, the patent lacked the "necessary link" between the two stages, because it did not teach how to find a compound which actually worked as a selective inhibitor. The court concluded that the patent gave "previous little guidance" on how to find such a suitable compound. The court states that "at most, its description will enable a person of ordinary skill in the art to attempt to discover [original emphasis] how to practice the claimed invention. That is not enough". Further, the District Court addressed the application of the written description requirement in regard to the method claims and determined that the '850 patent did not satisfy the written description requirement, citing the decisions in Lilly and Enzo. The court stated that the '850 patent did no more than describe the desired function of the compound required for the method. The court concluded that the patent did not succeed in taking the last critical step of actually identifying a suitable compound, or at least developing a process through which one of skill in the art would be directly led to such a compound.

The claims at issue in the Rochester v Searle are similar in nature to the instant invention. The instant specification teaches a method to identify a small molecule that modulates the interaction between ligand binding regions of α 2M receptor and HSP and binding fragment thereof. The specification provides teachings on how to use the

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small molecule test compound once it is identified as a modulator. The specification does not provide the necessary link between the two stages because it does not teach how to find a compound which actually works as a modulator. It is concluded that the specification gives no guidance at all on how to find a suitable compound without undue experimentation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher Yaen
Art unit 1642
May 3, 2005